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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,100	02/21/2002	Carlos F. Barbas III	TSRI 760.1	9900

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EXAMINER	
MCKELVEY, TERRY ALAN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,100	BARBAS ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005 and 07 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *7-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

In the Applicant's communication filed 4/7/05, the applicant's representative indicates that the Examiner and Michael McCarthy (the previous applicant's representative) had a telephone conference subsequent to the filing of a Response to an Office Action on February 10, 2005, and that the Examiner requested that a choice be made for further prosecution to one of: (1) allowing claim 1 if amended to recite only SEQ ID NO:46, (2) to search 10 sequences if designated by Applicant, or (3) to have an Ex parte Quayle action issued indicating that claim 1 is allowable if amended to limit to SEQ ID NO:46 in the absence of further action by Applicant, thereby limiting prosecution. The applicant elected 10 sequences, does not limit the claimed invention to those sequences, and instead, traverses the restriction requirement.

Several things about this telephone interview should be noted. First, this was intended to be a telephone interview to discuss the invention and the different ways that prosecution of the application could further occur. Instead of simply sending out an Ex Parte Quayle action, in the interests of compact prosecution, the examiner attempted to advance prosecution of the application to allowance by seeking permission for an examiner's amendment to place the application in condition for allowance.

Second, there was and is no unconditional agreement to search 10 sequences in the application, instead of just the original SEQ ID NO:46. The nature of the invention was discussed in the interview, including how much of the applicant's overall inventions was examined if the claims were limited to SEQ ID NO:46 and a potential compromise between an increased amount of the applicant's inventions searched and examined and the burden on the examiner by searching and examining that increased amount was discussed. The examiner indicated that he might be willing to consider searching and examining up to ten applicant-selected sequences (which includes previously elected SEQ ID NO:46) if there was no serious burden in doing so and if the applicant agreed to an examiner's amendment to limit the elected claims to those sequences minus

any of those sequences that read on the prior art identified in the expanded search, in order to place the application in condition for allowance. The applicant's representative gave no permission for the proposed examiner's amendment and thus the application was not placed into condition for allowance. Also, the communication from applicant's new representative, Michael Farber, filed April 7, 2005, does not constitute agreement to the proposed examiner's amendment. Therefore, in reality, the examiner did not agree to search and examine 10 sequences. And, as indicated below, it has been determined that serious burden does exist to extend the search and examination beyond the one elected sequence, and thus no examiner's amendment limiting the claimed invention to up to 10 sequences would have been possible had the applicant agreed to the proposed examiner's amendment.

The applicants also now traverse the election of Group I, claims 1-6, drawn to SEQ ID NO:46. The traversal is on the ground(s) that (1) the Official Gazette notice concerning sequences is drawn to independent and distinct nucleotide sequences, not polypeptide sequences as instantly claimed, and thus are not applicable to the Official Gazette notice, (2) that the restriction requirement being imposed means that Applicants are forced to abandon coverage of a substantial aspect of their

invention, a great degree of diversity in DNA binding, (3) the considerations for search of polypeptides are distinctly different than those for search of polynucleotides because of degeneracy and the probability of matches being far lower in polypeptides, and (4) that the applicant takes the (alleged) requirement to elect 10 sequences as a requirement for the election of species, which is traversed because the Examiner has not met the required burden for demonstrating the necessity for election because the subject matter of the heptapeptide or octapeptide sequences recited within the claims is sufficiently interrelated that no serious burden on the Examiner would exist if all of the sequences were examined on their merits because the art, if involved, if relevant art exists, largely overlaps, for example, publications describing nucleic acid sequences that encode polypeptides or protein typically, given the state of the art, recite variant sequences at both the nucleic acid and the peptide level, typically produced by site-specific mutagenesis or another technique. The applicant also argues (5) that all of the inventions are substantially related by the activity of the heptapeptide or octapeptide sequences in directing the binding of specific nucleotide sequences by these zinc finger polypeptides, that the existence of this common activity simplifies the search required and minimizes the burden on the

Examiner, so that a serious burden does not exist. The applicant argues (6) that claim 1 is a Markush-type claim claiming a number of species in the alternative, and that restriction between species recited in the alternative is not appropriate unless the subject matter in that claim lacks unity of invention, which the applicant argues exists because the polypeptides of claim 1 share a common utility, which is the sequence-specific binding of DNA by the zinc-finger moieties and they share a substantial structural feature disclosed as being essential to that utility, that substantial structural feature is the zinc finger motif itself, which is well-recognized in protein chemistry as a motif that confers specific nucleotide-sequence-binding capacity and has certain invariant structural features related to the amino acids that are directly involved in contacts with the bases of those nucleotides. The applicant also argues (7) that MPEP 806.03 applies, that all the claims are directed to isolated polypeptides that incorporate zinc finger heptapeptides or octapeptides and have the ability to bind specific trinucleotide sequences, specifically those with the residue adenine at their 3' end, and thus the pending claims define the same essential characteristics of a single disclosed embodiment of the invention.

First, it is noted that in response to the restriction requirement mailed 4/7/04, applicant elected Group I, claims 1-6, drawn to SEQ ID NO:46 without traverse on 5/10/04. If applicants desired to traverse the restriction requirement, applicants needed to have traversed the restriction requirement in the response to elect the invention to be examined, including presenting the arguments that are the actual traversal. The applicants chose not to traverse the restriction requirement and thus forfeited their traversal. Therefore, applicants' arguments late in prosecution traversing the restriction requirement after election of the invention to be examined without traverse are moot.

Second, if the applicants had timely presented their traversal of the election requirement, their arguments would not have been persuasive for the following reasons. The applicants' arguments are addressed in turn below, though repetitive arguments are addressed together.

(1) Since the applicant argues that the Official Gazette notice drawn to search and examination of up to 10 independent and distinct nucleotide sequences is not applicable to the claimed polypeptide sequences, and this notice also reads on requiring one sequence to be elected, which is what is required in the restriction requirement of record, the examiner, though

in disagreement, chooses not to argue the point. Therefore, the examiner agrees with the applicants' argument that the general principles governing restriction control the restriction requirement.

(2) The restriction requirement being imposed does not force the applicants to abandon coverage of a substantial aspect of their invention, a great degree of diversity in DNA binding because first, the applicants' invention is actually at least about 70 inventions, each drawn to a polypeptide comprising a particular heptapeptide or octapeptide, none of which are the same. The applicants are no more abandoning coverage of their "invention" (which is actually at least 70 inventions) than other applicants that, like the instant applicants, have to abandon (cancel) claims drawn to independent and/or distinct inventions. In other words, every applicant that cancels claims to non-elected inventions are also "abandoning coverage". Second, if applicants desire total coverage of the claimed subject matter that is drawn to about 70 inventions, applicant is free to file divisional applications drawn to the remaining inventions, resulting in the total coverage of the applicants' inventions. The restriction requirement does not restrict within a generic claim (which is actually what is prohibited in restriction practice). Claims 1-6 contain no generic claim that

is being restricted in such a fashion. The restriction is between independent and/or distinct inventions that are combined into a Markush-type claim, the members of which lack unity of invention which is further discussed below. Restriction between multiple independent and/or distinct inventions cannot be evaded by putting them together in a Markush-type claim that lacks unity of invention because restriction is between inventions, not claims.

(3) The degeneracy of the nucleic acid sequence versus polypeptide sequences have no real effect on the search burden because for simple cases, typically one nucleic acid sequence is set forth in the database for one particular amino acid sequence, a 1:1 ratio in the databases. For the more complicated cases, many different nucleic acid sequence fragments can be set forth for one polypeptide, but also many different amino acid sequence fragments can be set forth for one polynucleotide, so the degeneracy of nucleic acid sequences has no real effect on the database size and burden in searching. Although theoretically the probability of matches for a typical amino acid sequence of a given length is much lower than for a typical polynucleotide of the same length, in the instant case, for the elected invention, applicants are claiming any polypeptide comprising SEQ ID NO:46 which is an heptapeptide,

with further non-sequence limitations. Mathematically, the odds of finding matches for proteins having that very short sequence (7 amino acids) are much, much higher than for the more typical searches that are for much longer, full length proteins that are usually in the range of one to two hundred amino acids or more, or for polynucleotide sequences that are usually in the range of three to six hundred nucleotides or more. In other words, because the applicants' polypeptide of claim 1 drawn to SEQ ID NO:46 is limited to such a short sequence relative to most other proteins and polynucleotides that are searched by the USPTO, which other sequences are limited to searches for a single sequence, a search for one of the instant applicants' polypeptides results in many more hits than is typically seen in USPTO sequence searches. Each of these hits have to be evaluated for their applicability as prior art, including obtaining every document that is prior art by date, and evaluating each document to determine whether the sequence that is found within the document is in a polypeptide that meets the applicants' other non-sequence limitations: comprises 2 to 12 zinc finger-nucleotide and the sequence match is in a nucleotide binding region. This part of the search is much more burdensome than searching merely for sequence similarity which is the usual case for examination of polypeptides and polynucleotides. This

fact was highlighted when in preparation of the instant action, the examiner updated the sequence search for SEQ ID NO:46, including the search required for preparation of the allowance of claims 1-6 drawn to SEQ ID NO:46. This search proved to be much more burdensome than the examiner thought it would be. Based upon an estimate of the time it took for the final allowance search of SEQ ID NO:46 itself, a conservative estimate of the time it would take for doing the search and search evaluation that the applicants argue is not burdensome is actually 7 weeks. That is clearly too high of a burden for search, which is based upon searching and evaluating the search of 70 independent and/or distinct sequences. This is simply impossible based upon the USPTO fees that are currently charged and the corresponding short amount of time given examiners to search and examine a particular case (about 1 day for every thing needed to be completed for a final office action or allowance).

(4) The alleged requirement to elect 10 sequences is not correct for the reasons described above. The actual restriction requirement is drawn to the election of a polypeptide drawn to one sequence. It is not an election of species because the claimed polypeptides drawn to the different sequences such as SEQ ID NO:46 or one of the other sequences are drawn to

independent and/or distinct inventions because as shown by the applicants' 10 sequences that they "elect", the short polypeptides have no common sequence or structure, and thus all have to be searched in completely different sequence searches, thus requiring 10 different sequence searches to search the invention drawn to SEQ ID NOS:46-55. For example, SEQ ID NO:46 only has one amino acid in common with SEQ ID NO:47, "L" (leucine). These are unrelated sequences that cannot be searched together using one sequence search. It is the sequences of these short polypeptides that theoretically distinguish the claimed polypeptides over the prior art polypeptides because there are thousands or more polypeptides having the claimed non-sequence limitations of claim 1, comprising 2 to 12 zinc finger-nucleotide binding peptides, since many zinc finger containing polypeptides are known, most zinc finger containing polypeptides have two or more zinc fingers, and zinc finger polypeptides have been the subject of much experimentation and invention involving the mutagenesis of the zinc fingers of the polypeptides. Even if you consider the claimed polypeptide interrelated because of the non-sequence limitations to 2 to 12 zinc fingers, the applicants' claimed inventions are drawn to these proteins having particular sequence limitations which can only be realistically and

completely searched for by the means of a sequence search for each of the different sequences being searched for. The examiner simply cannot search for the claimed polypeptides based upon the nonsequence limitation: identify art that teaches polypeptides that have 2 to 12 zinc fingers, get all of that art (which is literally thousands or more documents), read each document, identify each nucleotide binding region for the zinc finger polypeptides in each document, and determine whether SEQ ID NO:46 or one of the other sequences is present in the binding region. Thus, the so-called interrelated aspect of the claimed polypeptides cannot be the basis of searching for the claimed invention in a non-burdensome fashion. The relevant art if it exists does not overlap because a document that teaches the claimed invention drawn to SEQ ID NO:46 does not necessarily (and probably does not) teach the claimed invention drawn to SEQ ID NO:47 (which is an independent and/or distinct sequence). Each polypeptide drawn to a different sequence requires a completely different and large search for the different short sequences.

(5) The alleged common activity is not common because although the different sequences bind specific nucleotide sequences (three nucleotides), they are not all the same specific nucleotide sequences, and, even if some of the

sequences bind the same nucleotide sequences, the amino acids of the claimed sequences are not in common and thus must each be searched separately because just "common activity" is not what is being claimed, but instead claims drawn to comprising different specific sequences are what is claimed and thus those sequences must each be searched in the sequence databases. The burden is thus not minimized.

(6) The different sequences in the Markush-type claim 1 do lack unity of invention because the polypeptides drawn to the different sequences do not have a common utility because each sequence is drawn to binding a different polynucleotide triplet, and the polypeptides comprising the different sequences do not share a substantial structural feature disclosed as being essential to that utility, because the distinguishing feature of the different claimed polypeptides is the different sequences that are comprised by the different polypeptides, which sequences are the ones that are responsible for the sequence-specific binding of the zinc fingers.

(7) The different polypeptides drawn to different sequences are not drawn to a single disclosed embodiment, but instead are drawn to about seventy embodiments each limited to a different short peptide sequence which is independent and/or distinct from the other sequences.

Therefore, even if the applicants had timely traversed the restriction requirement instead of electing the invention to be examined without traverse, the applicants' arguments would not have persuasive and the restriction requirement would have been shown to be proper.

This application is in condition for allowance except for the following formal matters:

Claim Objections

Claims 1-6 are objected to because of the following informalities: the claims are drawn to encompass non-elected inventions (comprising sequences that are independent and/or distinct from the elected sequence of SEQ ID NO:46). This objection is maintained for the reasons described below. The claims should be amended to only read on the elected invention which is drawn to SEQ ID NO:46. Appropriate correction is required.

In applicants' response filed 2/14/05, applicants argue that 35 USC 121 provides no legal authority to impose a rejection on a single claim, even if the claim presents multiple independently patentable inventions, citing and discussing In re

Weber. This argument is not persuasive because In re Weber does not apply because as is clearly stated in the cited quotations, refusal to examine a broad generic claim is what is not permitted in restrictions. This is not the case for claims 1-6 because claim 1 is not drawn to a generic claim, but instead, it is a Markush-type claim which claims about 70 independent and/or distinct inventions that lack unity of invention as discussed above. It is also incorrect that if the instant rejection is allowed to stand, Applicants will never be accorded the basic right of the applicant to claim his invention as he chooses. He can claim his invention as he chooses, but it doesn't mean that he has the right to have any number of independent and/or distinct inventions (such as 70!) examined in the same application. As a practical matter of not allowing applicants to overwhelm the examiner's limited time given for examination of a single application, the examiner has the right to restrict between independent and/or distinct inventions according to the principles set forth in the MPEP and require the applicant to choose an invention to be examined. Restriction between multiple independent and/or distinct inventions cannot be evaded by putting them together in a Markush-type claim that lacks unity of invention because restriction is between inventions, not claims.

Additionally, because the instant claims are not generic claims, the situation quoted in In re Weber is not the case for the instant claims: "If ... a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification." In the instant case, because claims 1 is a Markush-type claim, not a generic claim, the claim is easily divided into the independent and/or distinct members of the Markush-type group (which lacks unity of invention), which in the aggregate, would encompass the entire scope of claim 1 drawn to the 70 independent and/or distinct inventions. For example, claim 1 limited to SEQ ID NO:46 would read: "Claim 1. An isolated polypeptide comprising from 2 to 12 zinc finger-nucleotide binding peptides at least one of which peptides contains a nucleotide binding region having the sequence of SEQ ID NO:46." If applicants also want to explicitly encompass those isolated polypeptides that contain two or more of the recited sequences, then because this claim 1 does encompass any additional sequences as long as SEQ ID NO:46

is comprised, including comprising the other SEQ ID NOS, an explicit claim drawn to comprising one or more of those sequences can be claimed by the following dependent claim (presented in combination with above claim 1): "Claim 2. The isolated polypeptide of claim 1, wherein at least one of which peptides, other than the at least one of which peptides recited in claim 1, contains a nucleotide binding region having the sequence of any of SEQ ID NO:7-70 and 107-112." If these types of claims were presented in different divisional cases for the 70 independent and/or distinct inventions of instant claim 1, then applicant would get a complete examination of the scope of instant claim 1 which contains the 70 independent and/or distinct inventions.

Also, if the applicants' arguments were accepted, then the patent application examination system would fall apart from the serious burden due to examiners being overwhelmed because all applicants would place any number of independent and/or distinct inventions into Markush-type claims that lack unity of invention and expect the Patent Office to examine all of those inventions for the relatively low fees based upon the examination of one invention per case.

Finally, as a practical matter for the Office Action Summary, claims 1-6 cannot be given the status of "allowed",

because they are not allowed due to the presence of non-elected subject matter. Claims 1-6 are not "rejected" because the elected subject matter in those claims are not rejected. Claims 1-6 are not "withdrawn from consideration" because the elected subject matter of those claims are under consideration. That only leaves the possible status of "objected to", for the reason that the claims contain non-elected subject matter. This is due to Applicants' claiming their inventions in a Markush-type claim that lacks unity of invention.

This application is in condition for allowance except for the presence of claims 1-6 (drawn to SEQ ID NOS:7-45, 47-70, and 107-112) and claims 7-15 drawn to an invention non-elected without traverse on May 10, 2004. Although claims 7-15 can be canceled by the examiner in an examiner's amendment without further permission by the applicant because they are drawn to claims that are non-elected without traverse, the remaining claims, claims 1-6, also contain non-elected subject matter and thus cannot be canceled because such cancelation would also cancel the only elected subject matter (drawn to SEQ ID NO:46) and thus no claims would be allowable. Because applicants did not traverse the restriction requirement when electing the invention to be examined on 5/10/04, applicants forfeited their

right of petition of the restriction requirement. See MPEP 818.03(c) which is titled: "Must Traverse To Preserve Right of Petition". Therefore, applicants must cancel the non-elected subject matter in claims 1-6, by removing SEQ ID NOS: 7-45, 47-70, and 107-112 from claims 1-6 (and not adding any new non-elected subject matter), and canceling non-elected claims 7-15, in order to be responsive to the instant action. Any response that does not include cancelation of the non-elected subject matter and claims, elected without traverse on 5/10/04, will be considered non-responsive.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does*

submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and

history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Terry A McKelvey

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

June 22, 2005